STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner

v **File No. 121668-001**

Blue Cross Blue Shield of Michigan
Respondent

_____

Issued and entered
this _____ day of November 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On June 1, 2011, XXXXX, authorized representative of XXXXX (Petitioner), filed a request with the Commissioner of Financial and Insurance Regulation for an external review under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*. On June 8, 2011, after a preliminary review of the material submitted, the request was accepted.

The Petitioner has health care coverage through a group underwritten by Blue Cross and Blue Shield of Michigan (BCBSM). Her benefits are contained in the *Community Blue Group Benefits Certificate* (the certificate).

Because medical issues are involved, the case was assigned to an independent review organization which provided its analysis and recommendations on June 23, 2011.

II. FACTUAL BACKGROUND

The Petitioner received mobile cardiac outpatient telemetry (MCOT) monitoring from December 6, 2010 to December 26, 2010. MCOT is a system that captures and transmits arrhythmia information as it occurs. The amount charged for the technical component of this service was $4,500.00.

BCBM denied coverage, stating the MCOT was investigational. The Petitioner appealed the denial through BCBSM's internal grievance process. After a managerial-level conference on March 28, 2011, BCBSM did not change its decision and issued a final adverse determination dated March 30, 2011.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's MCOT?

IV. ANALYSIS

Petitioner's Argument

The Petitioner believes that the MCOT technical services that she received were medically necessary and a covered benefit under her certificate. She states this conclusion is supported by: her physician; the standard of care in the medical community; studies in peer-reviewed and other medical literature; the terms of the Petitioner's coverage; and applicable law. The Petitioner's authorized representative submitted documentation to support the use of MCOT given her diagnosis of syncope and collapse.

The Petitioner indicates this technology was approved by the FDA in November 1998 and the technical component is billed under CPT code 93229. She states MCOT monitoring for indications like hers have been used effectively by the medical community in the United States for over a decade and that many health plans, including Medicare, cover this service. She believes that BCBSM should cover her December 2010 MCOT services.

BCBSM's Argument

BCBSM argues that absent from the documentation provided by the Petitioner is anything that indicates the MCOT was necessary because conventional outpatient cardiac monitoring is ineffective. BCBSM's medical policy title "Real-Time Outpatient Cardiac Telemetry Monitoring" concludes:

> Real-time outpatient cardiac telemetry…is considered experimental/ investigational in patients who experienced symptoms suggestive of cardiac arrhythmias (i.e., palpitations, dizziness, presyncope or syncope). While this service may be safe, its effectiveness in capturing arrhythmias for immediate treatment, as opposed to conventional outpatient cardiac monitoring, has not been scientifically determined.

BCBSM believes the use of MCOT is investigational in the Petitioner's case. Since investigational devices are excluded from coverage in the certificate, BCBSM believes that it is not required to cover it.

Commissioner's Review

The certificate (p. 4.27) states that "experimental treatment" is not a payable service. "Experimental treatment" is defined (p. 7.9) as:

> Treatment that has not been scientifically proven to be as safe and effective for treatment of the patient's conditions as conventional treatment. Sometimes it is referred to as "investigational" or "experimental services."

The question of whether the Petitioner's MCOT was experimental for treatment of her condition was presented to an independent medical review organization (IRO) for analysis, as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician certified by the American Board of Internal Medicine with a subspecialty in cardiovascular disease, published in peer reviewed medical literature, and is in active practice. The reviewer's report included the following analysis:

> It is the determination of this reviewer that the mobile cardiovascular telemetry services/technical support is not considered experimental/investigative for [the Petitioner's] condition.
>
> **Clinical Rationale for the Decision:**
>
> The standard of care for [the Petitioner's] condition is a referral for a Holter monitor if there is clinical concern for palpitations and atrial fibrillation. If the Holter monitoring is non-diagnostic and/or symptoms are in frequent, as was the case in this patient, the standard of care is to then proceed with mobile cardiovascular telemetry.
>
> There is evidence in the clinical literature to support the notion that MCOT is more likely to capture and document symptomatic and asymptomatic arrhythmias. Olson et al concluded "MCOT can detect asymptomatic clinically significant arrhythmias, and was especially useful to identify the cause of presyncope/ syncope, even in patients with a previous negative workup. This outpatient monitoring system allows patients to undergo daily medication dose titration in the outpatient setting thus avoiding hospitalization."
>
> Rothman et al concluded "MCOT provided a significantly higher yield than standard cardiac loop recorders in patient with symptoms suggestive of a significant cardiac arrhythmia."

> In view of the data demonstrating that MCOT is more efficacious than standard loop monitors in detecting both symptomatic and asymptomatic arrhythmias, the use of this technology is not experimental/investigational. Its use in this case would be in keeping with the expected standards of care in the community.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO's recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner accepts the IRO recommendation and finds that MCOT is not experimental for treatment of Petitioner's condition.

V. ORDER

Respondent Blue Cross Blue Shield of Michigan's March 30, 2011, final adverse determination is reversed. BCBSM shall cover the Petitioner's 2010 mobile cardiac outpatient telemetry (MCOT) monitoring within 60 days from the date of this Order and shall, within seven (7) days of providing coverage, furnish the Commissioner with proof it has implemented this Order.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health Plans Division, toll free at (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton
Commissioner